



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,808	03/15/2000	Athanasius A Anagnostou	5218-39C	9764

20792 7590 02/06/2004

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/525,808

Applicant(s)

ANAGNOSTOU ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-22,31-33,35-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,18,21,22,31-33,35-38 and 40 is/are rejected.
- 7) ☒ Claim(s) 17,19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 10/31/2003 is acknowledged and entered into the record. Accordingly, claims 1-15, 23-30, 34, and 39 are canceled without prejudice or disclaimer, and claims 40 is newly added.
2. Claims 16-22, 31-33, 35-38, and 40 are pending and examined on the merits.

Information Disclosure Statement

3. The Information Disclosure Statement filed 9/02/2003 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

4. The rejection of claim 34 under 35 USC 112, 1st paragraph is moot in view of the cancellation of the claim.

Claim Rejections Withdrawn - 35 USC § 102

5. The rejection of claim 35, 36, and 38 under 35 USC 102(b) as being anticipated by Silvestris *et al* is withdrawn in view of the amendments to the claims. The rejection of claim 30 is moot in view of the cancellation of the claim.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 16, 31- 33 under 35 USC 102(b) as being anticipated by Silvestris *et al* is maintained for the reasons of record. Applicant states that the claims have been amended to specifically recite "cisplatin", however, Silvestris *et al* still

Art Unit: 1642

discloses a method of administering erythropoietin (epo) within the dose ranges that would help treat endothelial cell injury. Although it is not implicitly stated, the endothelial cells would be damaged because as stated in the specification and claimed, cancer is a cause for said endothelial cell injury.

New Arguments

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 16,18,21,22, 31,32,35, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 02 096535 (Chugai Pharm Co. Ltd., IDS #1 9/02/2003, see abstract). JP 02 096535 teaches a method of treating comprising the intravenous administration of epo in a subject wherein the damage is caused either exposure to radiation or to carcinogenic compounds, such as cisplatin. Because the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering EPO for the treatment of disease caused by the same mechanism (i.e. exposure to radiation or as a result of the treatment of cancer by carcinogenic compounds such as ciplatin), the claimed method is anticipated because the method will inherently treat endothelial cells that are damaged as a result of the aforementioned mechanisms of disease. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

9. Claims 16,21,31,32,33, and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bukowski *et al* (Blood 1994;84(10 Supp. 1):129A, IDS #3 9/02/2003).

Bukowski *et al* teach a method of administering epo to patients suffering from anemic cancer following chemotherapy. Bukowski *et al* also disclose the administration of epo in the dose ranges of 150-300 U/kg. Furthermore, Bukowski *et al* also disclose the concomitant administration of epo with cisplatin. Because the cancer lead to the administration of cisplatin, which results in the injury of endothelial cells, and because the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering EPO in conjunction or concomitantly with cisplatin within the same endothelial-inhibiting dosage range, the claimed method is anticipated because the method will inherently treat the injured endothelial cells. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Conclusion

10. No claim is allowed. Claims 17, 19-20 are objected to as being dependent upon a rejected base claim 16.

11. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 9/2/2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
February 3, 2004



LARRY R. HELMS, PH.D
PRIMARY EXAMINER